

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JEANNE LEBLANC
18 Ramble Road
Milford, Massachusetts 01757

and

RONALD J. LEBLANC
18 Ramble Road
Milford, Massachusetts 01757

Plaintiffs,

vs.

WYETH, INC.
5 Giralda Farms
Madison, New Jersey 07940

SERVE: Prentice Hall Corp. Systems
830 Bear Tavern Road
Trenton, NJ 08628

and

WYETH PHARMACEUTICALS INC.
500 Arcola Drive
Collegeville, Pennsylvania 19426

SERVE: Corporation Service Company:
2704 Commerce Drive
Harrisburg, PA 17110

and

PHARMACIA & UPJOHN COMPANY
100 Route 206 North
Peapack, New Jersey, 07977

SERVE: Corporation Trust Company
820 Bear Tavern Road
Trenton, NJ 08628

and

COMPLAINT AND JURY DEMAND

05-40102 FDS

Civil Action No. _____

RECEIPT # 404594
AMOUNT \$ 250
SUMMONS ISSUED ☒
LOCAL RULE 4.1 ☒
WAIVER FORM ☒
MCF ISSUED ☒
BY DPTY. CLK. S Jmer
DATE 6-24-05

PFIZER, INC.	:
235 East 42 nd Street	:
New York, New York, 10017	:
 SERVE: CT Corporation System	:
111 Eighth Avenue	:
New York, NY 10011	:
 Defendants.	:

NOW COME the Plaintiffs, Jeanne LeBlanc and Ronald J. LeBlanc, by and through their attorneys, James N. Wittorff, Robert K. Jenner, Kenneth M. Suggs and Janet, Jenner & Suggs, LLC, and for their cause of action, sue the Defendants, and state and allege as follows:

PREAMBLE

Since the first estrogen pill was introduced in 1942, makers of synthetic sex hormones have created a marketing and cultural phenomenon. Drug companies' claims to support the use of hormone therapy were never backed by reliable scientific evidence, despite a flood of drug-company promotions.

In July 2002, federal officials abruptly stopped a trial of hormone therapy drugs that was being conducted by the Women's Health Initiative (WHI). The WHI trial revealed that women taking Prempro, a combination of estrogen and progestin hormones, experienced an increased incidence of breast cancer, heart disease, and stroke. Another study published later the same month showed that women taking estrogen-only pills (*i.e.*, Premarin), are at greater risk to develop ovarian cancer. The *New England Journal of Medicine* concluded in February 2003, that the "risks of breast cancer, venous thromboembolism, and stroke are too high a price to pay" for unsubstantiated benefits of hormone therapy.

Subsequent studies following WHI demonstrate conclusively that evidence-based medicine took a back seat to "conventional wisdom." The *New England Journal of Medicine* wrote in October 2003:

The simple and intuitively appealing concept that replacing estrogen lost during menopause would be beneficial was easy for both patients and physicians to believe. . . . *As a result, many people suspended ordinary standards of evidence* concerning medical interventions . . . despite the absence of any large scale clinical trial quantifying its overall risk-benefit ratio. [Emphasis added].

The Plaintiffs in this lawsuit will prove that these hormone drugs were unreasonably dangerous for any long-term use, and that the Defendant(s) promoted synthetic hormone drug therapy without conducting appropriate long-term, clinical trials to support their claims. The Plaintiffs will further prove that Defendants Wyeth and the MPA Defendants pushed hormone therapy onto the medical community, without sufficient warnings. Had Wyeth, and the MPA Defendants acted appropriately, thousands of women nationwide, and the Plaintiff herein, would not have been injured by these drugs.

I. PARTIES

1. Plaintiff Jeanne LeBlanc is a United States citizen, residing at 18 Ramble Road, Milford, Worcester County, Massachusetts.
2. Plaintiff Ronald J. LeBlanc is a United States citizen, residing at 18 Ramble Road, Milford, Worcester County, Massachusetts.
3. Wyeth, Inc. is a Delaware corporation with a principal place of business located at 5 Giralda Farms, Madison, New Jersey. At all times relevant hereto, Wyeth was engaged in Massachusetts, in the testing, manufacturing, labeling, marketing, distributing, promoting, and selling of hormone therapy drugs, including Premarin, Prempro, Premphase and medroxyprogesterone acetate.
4. Wyeth Pharmaceuticals Inc. is a Delaware corporation with headquarters and a principal place of business located at 500 Arcola Drive, Collegeville, Pennsylvania. At all times relevant hereto, Wyeth Pharmaceuticals Inc., was engaged in Massachusetts, in the testing, manufacturing, labeling, marketing, distributing, promoting, and selling of hormone therapy drugs, including Premarin, Prempro, Premphase and medroxyprogesterone acetate.
5. Pharmacia & Upjohn Company is a Delaware corporation headquartered and with a principal place of business at 100 Route 206 North, Peapack, New Jersey. At all times relevant hereto, Pharmacia & Upjohn Company was engaged in,

inter alia, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including medroxyprogesterone acetate. Plaintiff alleges on information and belief that Pharmacia & Upjohn Company does business in Massachusetts and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drug medroxyprogesterone acetate.

6. Pfizer, Inc. is a Delaware corporation headquartered and with a principal place of business at 235 East 42nd Street, New York, New York. At all times relevant hereto, Pfizer, Inc. was engaged in, *inter alia*, the business of testing, manufacturing, labeling, marketing, distributing, promoting, and selling hormone therapy drugs, including medroxyprogesterone acetate. Plaintiff alleges on information and belief that Pfizer, Inc. does business in Massachusetts and, at all times relevant hereto, it tested, manufactured, labeled, marketed, distributed, promoted, and sold the drug medroxyprogesterone acetate.

II. JURISDICTION/VENUE

7. The amount in controversy exceeds seventy-five thousand dollars (\$75,000.00) exclusive of costs and interest, and diversity jurisdiction exists pursuant to 28 U.S.C. §1332.
8. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391.
9. The Defendants committed a tortious act within Massachusetts causing injury to Plaintiffs. Defendants regularly do or solicit business or engage in other persistent courses of conduct or derive substantial revenues from goods used and consumed in Massachusetts, or for services rendered in Massachusetts, and said Defendants expected or reasonably should have expected that their tortious acts would have consequences in Massachusetts, and Defendants derive substantial revenue from interstate and/or international commerce, including Massachusetts.
10. The Defendants committed a tortious act within Massachusetts by marketing, distributing, retailing and selling a dangerous and defective drug within Massachusetts to Plaintiff Jeanne LeBlanc and/or anyone else who may have consumed the defective product, and did cause serious and permanent injury to the Plaintiff.
11. The Defendants regularly solicited business within Massachusetts and engaged in the persistent course of conduct of distributing, retailing and transporting certain of its products within Massachusetts and to many of the other states within the United States, and derived substantial revenues from goods or services rendered in Massachusetts.

III. FACTUAL BACKGROUND

A. Case Specific Facts

12. From approximately 1990 through the present, Jeanne LeBlanc was under the routine gynecological care of Kathryn Cohan, M.D. of Milford, Massachusetts.
13. In approximately 1990, Dr. Cohan prescribed Premarin and Provera to Mrs. LeBlanc.
14. At some point after 1995, Dr. Cohan changed her hormone therapy prescription to Prempro. Mrs. LeBlanc continued to take Prempro, as prescribed, through February 2001.
15. During her course of treatment with Prempro, Mrs. LeBlanc continued to undergo routine check-ups.
16. Mrs. LeBlanc noticed left breast abnormalities in approximately January 2001 and called Dr. Cohan for an appointment. On or about January 8, 2001, Dr. Cohan noted the left breast abnormalities and referred Mrs. LeBlanc to Thomas Maki, M.D. for follow-up medical care.
17. Dr. Maki drained fluid from two areas in the left breast. The pathology report showed slight atypia. Therefore, on February 16, 2001, Mrs. LeBlanc underwent a biopsy of her left breast and was subsequently diagnosed with infiltrating lobular carcinoma with positive estrogen and progesterone receptors.
18. On April 16, 2001, Mrs. LeBlanc underwent a left mastectomy.
19. Mrs. LeBlanc received chemotherapy treatment from May 2001 through July 2001, and began taking Tamoxifen. She underwent left breast reconstructive surgery and a reduction of the right breast on May 17, 2002.
20. A routine chest CT scan on July 8, 2002 showed an abnormal soft tissue density and several hepatic lesions. A liver biopsy was performed on July 30, 2002, which showed metastatic carcinoma consistent with primary breast cancer. She began radiation treatment, chemotherapy treatment that continues to the present day and also takes Arimidex. Mrs. LeBlanc will receive chemotherapy treatment for the rest of her life.
21. As a direct result of being prescribed and taking Premarin, Provera and Prempro, Plaintiff Jeanne LeBlanc was diagnosed with infiltrating lobular breast cancer, suffered severe conscious pain and suffering, untold physical disfigurement, embarrassment, mental anguish, loss of confidence, a shortened life, lost economic benefits as well as expenses for care, treatment and hospitalization among other damages.

B. The Marketing of Hormone Therapy

22. Menopause is the cessation of menstruation caused by declining levels of estrogen and progesterone. It is a natural human phenomenon -- a phase of the female reproductive aging process -- not a disease. Symptoms, which vary in severity from woman to woman, may include hot flashes, chills, vaginal dryness, headache, and irritability. Adverse consequences of the drop in estrogen levels, which begin with menopause and continue after menopause, include, *inter alia*, vaginal atrophy and dryness; an increase in LDL cholesterol levels; and, a decrease in bone density with resultant increased risk of osteoporosis.
23. These symptoms and consequences of menopause have been described in scientific literature since the late 1800s, and by the turn of the 20th century, the search for an aid to alleviate them was widely pursued.
24. In 1942, Ayerst, the predecessor to Wyeth, received patent and FDA approval for Premarin, a mix of estrogens extracted from the urine of pregnant mares. Premarin was marketed to women and their physicians as the long sought after replacement for lost estrogen in menopausal women, and was referred to as "replacement" estrogen therapy.
25. The FDA originally approved Premarin only to relieve menopausal symptoms, such as hot flashes and vaginal atrophy. Wyeth, however, has long touted additional benefits for Premarin, and its subsequently marketed hormone therapy drugs, Prempro, Premphase and medroxyprogesterone acetate.
26. In the 1960s, Wyeth's Premarin promotional materials used articles and books written by Dr. Robert Wilson. Dr. Wilson, a Brooklyn, New York, gynecologist, recommended that women use Premarin for reasons far beyond those approved by the FDA. In a 1962 article which appeared in the *Journal of the American Medical Association (JAMA)*, Dr. Wilson claimed that taking estrogen during menopause *reduced* breast and genital cancers. In his 1966 book, Feminine Forever— which Wyeth's sales forces distributed to physicians throughout the country – Dr. Wilson wrote that "aside from keeping a woman sexually attractive and potent . . . estrogen preserves the strength of her bones, the glow of her skin, the gloss of her hair. . . . Estrogen makes women adaptable, even-tempered, and generally easy to live with." In the book, Dr. Wilson again asserted that estrogen prevented cancers.

27. Following Dr. Wilson's publications, sales of Premarin quadrupled. Wyeth poured thousands of dollars into Dr. Wilson's research. By the mid-1970s, more than 30 million prescriptions for Premarin were being written every year, eventually making it the fifth most frequently prescribed drug in the United States.
28. Physicians were instructed in advertisements to prescribe Premarin to achieve "tranquilizing" effects for their female patients – as if that effect was a laudable goal: "Almost any tranquilizer might calm her down . . . but at her age, estrogen may be what she really needs."
29. The promotional advertising downplayed the risks of hormone therapy and over promoted the benefits. A 1970s article in *Harper's Bazaar* claimed: "There doesn't seem to be a sexy thing estrogen can't and won't do to keep you flirtatiously feminine for the rest of your days . . . a real package deal that spruces up your vagina. . . . Prevalent medical opinion is that the safety and benefits of ERT have been convincingly demonstrated."¹
30. But the "safety and benefits" of Premarin were cast in serious doubt following a 1976 study published in the *New England Journal of Medicine* evidencing a causal relationship between estrogen and endometrial cancer. Sales plummeted, and physicians stopped prescribing Premarin except to those women who had hysterectomies and thus were not at risk for endometrial cancer.
31. A 1980 medical article suggested a solution. Dr. Don Gambrell, a reproductive endocrinologist, reported in the journal *Obstetrics and Gynecology* that adding progestin to estrogen led to a *decline* in endometrial cancer. Wyeth thus produced and marketed progestin (i.e., synthetic progesterone or medroxyprogesterone acetate) as an adjunct to Premarin estrogen hormone therapy to protect against the risk of endometrial cancer.
32. Wyeth manufactures, sells and distributes medroxyprogesterone acetate for use in combination with Premarin under trademarked brand names such as Provera and Cycrin, and as generic equivalents. And, Prempro has the added synthetic progesterone.
33. Additional claims were made in the 1980s when Wyeth promoted hormone therapy to help prevent bone loss, and when Wyeth claimed that hormone therapy drugs could prevent cardiovascular disease. By claiming that hormone therapy

¹ "ERT" is shorthand for Estrogen Replacement Therapy (e.g., Premarin taken alone).

drugs prevented osteoporosis and cardiovascular disease. Wyeth was able to promote Premarin as recommended treatment for all women, regardless of whether they were experiencing menopause. As a result, between 1990 and 1995, Premarin became the most frequently dispensed prescription drug in the United States.

34. Premarin's huge success was bolstered by claims that indefinite, long term use of estrogen therapy was safe and efficacious. In an early 1990s promotional videotape distributed directly to consumers entitled *"What Every Woman Should Know About Estrogen,"* Wyeth represented to women that estrogen provided "long term health protection" and should be continued indefinitely, even after short-term menopausal symptoms, such as hot flashes, had subsided. When a purported consumer inquired how long Premarin should be taken, Wyeth's doctor-spokesperson responded, "Anywhere from five to ten years in order to get protection from long term problems." And, with regard to breast cancer risks, Wyeth represented to women that the benefits of taking estrogen "far outweigh[ed]" the risks for women unless they faced a particularly high risk of breast cancer.
35. Prior to 1995, Wyeth began to develop a combination therapy pill that would combine Premarin with progestin. This product development was necessary because Wyeth faced the threat of a shrinking market for Premarin at the end of its patent protection in 1995.
36. In 1995 Wyeth introduced Prempro, "combination" hormone therapy that contained estrogen and medroxyprogesterone acetate (synthetic progestins).
37. Wyeth led physicians and consumers to believe the promotional claims it made regarding Premarin. Likewise, when Wyeth introduced Prempro to the market, physicians and consumers were again led to believe that these attributes existed for this hormone therapy, as Wyeth had claimed about Premarin.
38. Wyeth over-promoted Prempro, just as it did Premarin. For example, Wyeth distributed a brochure that asked women to "Take a few minutes to think about the rest of your life," and then listed medical conditions to "think about" which neither Prempro nor Premarin had been approved by the FDA to treat, including Alzheimer's disease, vision problems, tooth loss, heart disease, and colon cancer.
39. In a magazine advertisement featuring model Lauren Hutten, Wyeth made a rash of similar claims, suggesting that its hormone therapy drugs were appropriate for treating or preventing, among other things, memory loss, colon cancer, and

age-related vision loss. In the March 19, 2000, edition of *Parade Magazine*, Wyeth spokesperson Lauren Hutton (who was not identified as a Wyeth spokesperson) was asked what she did to look good and feel fit, and she answered: “[M]y number one secret is estrogen. It’s good for your moods; it’s good for your skin. If I had to choose between all my creams and makeup for feeling and looking good, I’d take the estrogen.

40. Wyeth’s DTC (i.e., “direct-to-consumer” or “DTC” marketing) efforts have included overt advertising pieces, such as print advertisements, videotapes, and brochures directed to consumers, as well as “product placement” efforts in which hormone therapy drugs are favorably positioned in entertainment vehicles or favorably described in the popular press by hired spokespersons.
41. Wyeth vigorously promoted hormone therapy to physicians, as well as to consumers directly. In 1999, Wyeth spent \$34.7 million on DTC advertising for Prempro. In 2000, Wyeth spent \$37.4 million on Prempro DTC advertising. The thrust of Wyeth’s marketing efforts has been to create a lifelong consumer demand for hormone therapy, and a belief by physicians that the prescription is beneficial to menopausal and post-menopausal patients.

C. The WHI and NCI Studies

42. Wyeth’s promotion of hormone therapy for long-term use proved false and misleading when studies released in July 2002 showed that such use substantially increases the risk of *causing* disease.
43. Two large cohort studies concluded that the risks of hormone therapy outweighed the benefits for most women: The WHI study, reported at Roussow JE, et al., *Risks and Benefits of Estrogen Plus Progestin in Healthy Post-menopausal Women*. (JAMA. 2002 Jul 17; 288:321-33.); and, the NCI study, reported at Lacey JV Jr., et al., *Menopausal Hormone Replacement Therapy and Risk of Ovarian Cancer*. (JAMA. 2002 Jul 17; 288(3):334-41.)
44. The Women’s Health Initiative (WHI) is a group focused on defining the risks and benefits of strategies that could potentially reduce the incidence of heart disease, breast and colorectal cancer, and fractures in post-menopausal women. Between 1993 and 1998, the WHI enrolled 161,809 post-menopausal women in the age range of 50 to 79 years into a set of clinical trials and an observational study at 40 clinical centers in the United States. Included within the clinical trials was a study by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health (NIH).

45. Participants in the NHLBI component of WHI, like most women with a uterus who take hormone therapy, were given progestin in combination with estrogen (i.e., combination hormone therapy). The estrogen plus progestin trial of the WHI involved 16,608 women ages 50 to 79 years with an intact uterus. An important objective of the trial was to examine the effect of estrogen plus progestin on the prevention of heart disease and hip fractures, and any associated change in risk for breast and colon cancer. The study did not immediately address the short-term risks and benefits of hormones for the treatment of menopausal symptoms.
46. Women enrolled in the estrogen plus progestin study were randomly assigned to a daily dose of estrogen plus progestin (0.625 mg of conjugated equine estrogens plus 2.5 mg of medroxyprogesterone acetate) or to a placebo. Those participants receiving the drug (not placebo) received Wyeth's drug Prempro. Participants were enrolled in the study between 1993 and 1998 at over 40 clinical sites across the country.
47. In 2000 and again in 2001, WHI investigators complied with a recommendation from the study's Data and Safety Monitoring Board (DSMB) to inform participants of a small increase in heart attacks, strokes, and blood clots in women taking hormones. The DSMB, an independent advisory committee charged with reviewing results and ensuring participant safety, found that the actual number of women having any one of these events was small and did not cross the statistical boundary established to ensure participant safety. Therefore, the group recommended continuing the trial due to the still uncertain balance of risks and benefits.
48. At the DSMB's meeting on May 31, 2002, the data review revealed for the first time that the number of cases of invasive breast cancer in the estrogen plus progestin group had crossed the boundary established as a signal of increased risk. The DSMB's May 31, 2002 recommendation to stop the trial was based on the finding of increased breast cancer risk, supported by the evidence of overall health risks exceeding any benefits. On July 8, 2002, participants started receiving letters informing them about the results and telling them that they should stop study medications.
49. The WHI Study found that for the estrogen plus progestin group (i.e., those women who took Prempro) compared to placebo, overall there was a:
- (i) 41 percent increase in strokes,
 - (ii) 29 percent increase in heart attacks,

- (iii) 100 percent increase in venous thromboembolism (blood clots),
- (iv) 22 percent increase in total cardiovascular disease,
- (v) 26 percent increase in breast cancer,
- (vi) 37 percent reduction in cases of colorectal cancer, and
- (vii) one-third reduction in hip fracture rates.

50. The WHI Study concluded that the "Overall health risks exceeded benefits from use of combined estrogen plus progestin for an average 5.2-year follow-up among healthy post-menopausal US women." The Study also found that the combination hormone regimen should not be initiated or continued for primary prevention of coronary heart disease.
51. Because of the importance of the report from the WHI investigators on the estrogen plus progestin study, the study was released early to the public on July 9, 2002, as an expedited article on the *JAMA* Website. In commenting on the studies findings, NHLBI Director, Dr. Claude Lenfant, was unequivocal in his own conclusions:

The cardiovascular and cancer risks of estrogen plus progestin outweigh any benefits—and a 26 percent increase in breast cancer risk is too high a price to pay, even if there were a heart benefit. Similarly, the risks outweigh the benefits of fewer hip fractures.

52. Dr. Jacques Roussow, acting director of the WHI and lead author of the *JAMA* article, summarized the risks of combination hormone therapy in a very straightforward manner as he explained the statistical significance of the study results:

The WHI results tell us that during one year, among 10,000 post-menopausal women with a uterus who are taking estrogen plus progestin, *eight more will have invasive breast cancer, seven more will have a heart attack, eight more will have a stroke, and 18 more will have blood clots, including eight with blood clots in the lungs*, than will a similar group of 10,000 women not taking these hormones. This is a relatively small annual increase in

risk for an individual woman. Individual women who have participated in the trial and women in the population who have been on estrogen and progestin should not be unduly alarmed. However, even small individual risks over time, and on a population-wide basis, add up to *tens of thousands of these serious adverse health events*.

(Emphasis added.)

53. Within a week after the WHI results were reported, another article appeared in JAMA related to the risk of long-term use of estrogen-only therapy. On July 17, 2002, JAMA published a NCI study, which found that women who took estrogen were more likely to develop ovarian cancer than those not on the hormone.
54. In the study, researchers from the NCI followed 44,241 women for 19 years who were taking only estrogen and found that these women had a 60 percent higher risk of ovarian cancer than women who had never used estrogen. The risk increased proportionately with longer duration of estrogen use. Women who took estrogen for 10 to 19 years had an 80 percent higher risk than those who did not take the pills. Those on the hormone therapy for 20 years or more were three times as likely to develop ovarian cancer as women who did not take it at all. Most of the NCI participants used Wyeth's brand of estrogen therapy, Premarin.
55. Lead author of the NCI study, Dr. James V. Lacey, summarized the results of his study with the following statement:

The main finding of our study was that post-menopausal women who used estrogen replacement therapy for 10 or more years were at significantly higher risk of developing ovarian cancer than women who never used hormone replacement therapy.
56. Dr. Lacey further underscored the implications of his NCI study by explaining that the findings translate into one or two additional ovarian cancers each year per 10,000 women taking estrogen alone. In 2000, eight million American women

took Premarin, the leading estrogen therapy pill. The Lacey study demonstrates that Premarin usage is responsible for up to 1,600 additional ovarian cancer cases in the year 2000 alone.

57. In October 2003, the WHI study produced a report with findings similar to the NCI study regarding ovarian cancer. The October 1, 2003, issue of JAMA reported that combination hormone therapy was also associated with increased risk for ovarian cancer: the WHI investigators found that women randomized to received combined hormone therapy (i.e., estrogen plus progestin) experienced a 58 percent increase in ovarian cancer rates.

D. The Aftermath of the WHI and NCI Studies

58. The WHI and NCI studies received enormous media coverage: front-page newspaper headlines, magazine covers, and broadcast news programs urgently reported the alarming and significant findings.

59. Commenting on the WHI study, Dr. Leslie Ford, associate director for clinical research at the NCI's Division of Cancer Prevention, re-emphasized the risk of hormone therapy to patients:

The reduction in colorectal cancer risk in the WHI is intriguing, but the balance of harm versus benefit does not justify any woman beginning or continuing to take estrogen plus progestin for this purpose.

60. Dr. Isaac Schiff of Massachusetts General Hospital also commented on the WHI study, noting, "Quality of life is very, very important From a heart and breast cancer point of view, the drug should be outlawed. But for hot flashes, there's nothing better."

61. The WHI and NCI study conclusions regarding the unsafe and dangerous adverse effects of hormone therapy have been verified by subsequent published research. A study on hormone therapy and breast carcinoma risk in Hispanic and non-Hispanic women, reported on September 1, 2002, in the journal *Cancer*, found that Hispanic post-menopausal women have significantly increased breast cancer risk after long-term hormone therapy.

62. On October 23, 2002, the United Kingdom's Medical Research Council announced that it had ended a clinical study of the risks and benefits of long-term use of hormone therapy for "scientific and practical reasons." Approximately 5,700 women were enrolled in the "WISDOM" study (the Women's International Study of Long Duration Oestrogen after Menopause). The study was to include 22,000 women. However, following the WHI study, the WISDOM study was

- canceled. The Medical Research Council concluded "There is strong evidence that taking hormone therapy long term increases the risks of some diseases such as breast cancer and decreases the risks of others such as osteoporosis."
63. Because of the significance of its findings, on March 17, 2003, the New England Journal of Medicine (NEJM) released a follow-up WHI study two months in advance of its May 8, 2003 publication date. The follow-up study reported that hormone therapy failed to improve the quality of life for menopausal women.
64. The "Quality of Life" study which examined the same pool of 16,000 women as the July 9, 2002, WHI study, found that hormone therapy drugs do not do the very thing many women took them for in the first place, that is, to make them feel happier and healthier after menopause. A comparison of women who took hormone therapy to women given a placebo showed those women taking hormones did not report sleeping better or feeling better. The hormone therapy group also did not report feeling less depressed or more sexual satisfaction than the placebo group.
65. According to the study's lead author, Dr. Jennifer Hays: "It's just not something that's going to make most women feel better. Even if it reduces your symptoms, that's not going to translate into a meaningful effect on a quality of life." Dr. Deborah Grady of the University of California, in an accompanying commentary in same issue of the NEJM, said that: "There is no role for hormone therapy in the treatment of women without menopausal symptoms," and that only women who were experiencing debilitating menopausal symptoms should take hormone therapy. She stated further that those women who do continue with hormone therapy should take the lowest possible dose for the shortest possible time.
66. On May 21, 2003, JAMA published another study regarding the efficacy of estrogen plus progestin therapy (e.g., Prempro) for prevention of bone loss in elderly women. The study involved 373 women ages 65 to 90 who had either thinning bones or full-blown osteoporosis and took one of four treatments for three years: (i) combination hormone therapy alone, (ii) a bone-building drug, alendronate (which is sold under the brand name, Fosamax), (iii) combination hormone therapy with Fosamax, or (iv) a placebo.
67. While the study found that the combination of hormone therapy and Fosamax was effective at treatment and prevention of post-menopausal osteoporosis, it also concluded that Fosamax alone was more effective than combination hormone therapy alone. After three years, hip bone density had increased nearly six percent in women on hormone therapy with Fosamax, four percent in those on Fosamax alone, and three percent in the hormones-only group.

68. WHI researcher Dr. Hays, the lead author of the May 8, 2003 JAMA study on hormone therapy and quality of life, said that the findings of the bone-loss study are not convincing enough to recommend hormone therapy for osteoporosis prevention even in older women, especially because the study showed that the bone-enhancing benefits from estrogen come only after long-term use which also carries the highest risk of breast cancer or heart disease.
69. On May 28, 2003, JAMA published yet another study on the effects of hormone therapy, this time focusing on the risk of Alzheimer's disease and other types of dementia. The study found that combination hormone therapy, consisting of both estrogen and progestin, doubled the risk of dementia for woman who started hormones at age 65 or older.
70. The dementia study was based on a four-year experiment involving 4,532 women at 39 medical centers, where half took placebos and half took Prempro. In four years, there were 40 cases of dementia in the Prempro group and 21 in the placebo group. Translated to an annual rate for the population-at-large, the results mean that for every 10,000 women 65 and older taking hormone therapy, there will be 45 cases of dementia a year with 23 of them attributable to hormone use.
71. Dr. Sally A. Shumaker, the director of the dementia study and a professor of public health sciences at Wake Forest University, stated that the study's "clear message is that there's no reason for older women to be taking combination hormone therapy."
72. On June 25, 2003, JAMA published still another study analyzing the data from the Women's Health Initiative, which found that in addition to stimulating the growth of breast cancer, combination hormone therapy makes breast tumors harder to detect, leading to dangerous delays in diagnosis. The report found that breast abnormalities could develop soon after a woman starts taking hormone therapy. Consequently, the study's findings raise questions about the safety of even short-term hormone use. In the same June 25, 2003, issue that reported this study, JAMA also published an editorial by Dr. Peter H. Gann, a cancer epidemiologist at Northwestern University, who stated that this study represents "further compelling evidence against the use of combination estrogen plus progestin hormone therapy."
73. The connection between hormone therapy usage and breast cancer found in the WHI studies were confirmed by a similar study conducted in the United Kingdom. The August 9, 2003, issue of Lancet reported on the conclusions reached by *The Million Women Study* – a major research effort funded by Cancer Research UK – confirming that current and recent

use of hormone therapy increases a woman's chance of developing breast cancer, and that the risk increases with duration of use. Scientists at the Cancer Research UK analyzed data from over one million women between the ages of 50 and 64. Researchers found that post-menopausal women using combination hormone therapy were twice as likely to develop breast cancer as non-users (a 100% increase).

74. In the August 7, 2003, issue of *NEJM*, the WHI study continued to yield important information regarding the safety of hormone therapy use. The study found that combination hormone therapy does not protect the heart and may even increase the risk of coronary heart disease (CHD). Specifically, the WHI study found that combination hormone therapy usage was associated with a 24% overall increase in the risk of CHD (6 more heart attacks annually per 10,000 women using combination therapy) and a 81% increased risk of CHD in the first year after starting combination therapy.
75. In addition to the studies published in *JAMA*, *NEJM*, and other medical journals, a recent federal agency report also revealed that estrogen could be dangerous to women taking it as hormone therapy. On December 11, 2002, the National Institute of Environmental Health Sciences released its tenth annual report on carcinogens, which declared for the first time that estrogen is now on the federal government's list of "known human carcinogens."

E. Wyeth Changes Hormone Labels and Reverses Long-Term Marketing Strategy

76. In light of the WHI and NCI studies and other subsequent research reports, the labels provided by Wyeth for its Premarin and Prempro drugs were inadequate, misleading, and inaccurate. In fact, Wyeth changed warning labels on Premarin and Prempro during the last week of August, 2002 to reflect the results of the July, 2002 WHI and NCI studies.
77. Prior to the label change in August, 2002, the Premarin warning label made no mention whatsoever of ovarian cancer.
78. The Prempro label warnings were likewise inadequate prior to August, 2002. As to breast cancer, the Prempro warning explains the risk of breast cancer with conjugated estrogens (the Premarin component of Prempro), but then adds, with regard to the effect of added progestins on the risk of breast cancer: "The overall incidence of breast cancer does not exceed that expected in the general population." The WHI study plainly reveals that this warning is false and was known or should have been known by Wyeth to be false for decades.
79. The Prempro warnings were also inadequate for two thromboembolic disorders, pulmonary embolisms and blood clots: "The increased risk [of venous thromboembolism] was found only in current ERT [i.e., Premarin only] users."

Furthermore, as to cardiovascular disease (heart attacks and strokes), the Prempro warning reads simply, "Embolic cerebrovascular events and myocardial infarctions have been reported," without disclosing the true nature of the risk.

80. Under precautions, the Prempro label acknowledges: "The effects of estrogen replacement therapy on the risk of cardiovascular disease have not been adequately studied." Nevertheless, Wyeth has long promoted the supposed benefits of long term hormone therapy for cardiovascular disease.

81. On January 6, 2003, Wyeth abandoned its long-standing marketing strategy of promoting the long-term use of Premarin and Prempro. Wyeth announced the reversal of its long-held promotional message in a "Dear Doctor" letter to Health Care Professionals that explained it was adopting new labeling for its hormone therapy drugs in light of the WHI findings.

82. According to the January 6, 2003, "Dear Doctor" letter, the labeling changes include boxed warnings:

[W]hich state that estrogens and estrogens plus progestin therapies should not be used for prevention of cardiovascular disease . . . The boxed warning also includes information [stating that because of the WHI study] . . . estrogens and estrogens plus progestin ***should be prescribed for the shortest duration consistent with treatment goals.***

(Emphasis added.)

83. In early June 2003, Wyeth commenced a new public marketing campaign with a full-page advertisement placed in 180 newspapers nationwide. The advertisement, *"A Message from Wyeth,"* disclosed that Wyeth was abandoning its decades-long strategy of promoting long-term usage of Premarin and Prempro for post-menopausal women for a variety of conditions.

Hormone therapy is not a lifelong commitment. As a result of recent studies, we know that hormone therapy should not be used to prevent heart disease. These studies also report an increased risk of heart attack, stroke, breast cancer, blood clots, and dementia. Therefore, it is recommended that hormone therapy (estrogen, either alone or with progestin) ***should be taken for the shortest duration*** at the lowest effective dose.

(*The Philadelphia Inquirer*, June 1, 2003, at C6; emphasis added).

84. Wyeth had recklessly and willfully failed to conduct adequate pre-approval research and post-approval surveillance to establish the safety of long-term hormone therapy. Nonetheless, Wyeth had promoted long-term hormone therapy use

vigorously. The WHI and NCI studies could have and should have been conducted many years ago by Wyeth, before it began its long-term usage marketing campaign. Had it conducted the necessary studies and diligent post-marketing surveillance, Wyeth would have learned years ago that hormone therapy causes cardiovascular diseases, is marginally effective in preventing bone loss, does not promote well-being, causes a number of cancers and dementia, and is even harmful on a short-term basis by increasing the risk of breast cancer.

IV. FRAUDULENT CONCEALMENT

85. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of the facts as alleged herein by the Defendants. Plaintiffs have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part. Plaintiffs could not reasonably have discovered the dangerous nature of, and unreasonable adverse side effects associated with Premarin, Provera and Prempro prior to July 9, 2002.
86. The Defendants were and are under a continuing duty to disclose to Plaintiffs the true character, quality, and nature of their hormone therapy drugs, including Premarin, Provera and Prempro. Because of their concealment of the true character, quality and nature of their hormone therapy drugs, Defendants are estopped from relying on any statute of limitations defense.

V. CAUSES OF ACTION

COUNT I – NEGLIGENCE

87. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:
88. At all relevant times, Defendants had a duty to exercise reasonable care, and to comply with the existing standard of care, in its preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion, and sales of its hormone therapy drugs, including Wyeth's Premarin and Prempro, and Pharmacia and Upjohn's Provera, which they respectively introduced into the stream of commerce, including a duty to insure their hormone therapy drugs did not cause users to suffer from unreasonable, dangerous or untoward adverse side effects.

89. At all times relevant, Defendants owed a duty to warn consumers of the risks, dangers, and adverse side effects of its hormone therapy drugs properly.
90. Defendants breached their duty of care, and failed to exercise ordinary care in the preparation, design, research, development, manufacturing, inspection, labeling, marketing, promotion, and selling of their hormone therapy drugs, including Premarin, Provera and Prempro, which it introduced into the stream of commerce, because Defendants knew or should have known that its hormone therapy drugs created the risk of unreasonable, dangerous or untoward adverse side effects.
91. Defendants knew, or in the exercise of reasonable care, should have known that its hormone therapy drugs, including Premarin, Provera and Prempro were of such a nature that, if not properly prepared, designed, researched, developed, manufactured, inspected, labeled, marketed, promoted, and sold, they were likely to cause injury to those who took their drugs.
92. Defendants breached their duty of care, and failed to use due care, in the manner in which they prepared, designed, researched, developed, manufactured, inspected, labeled, marketed, promoted, and sold their hormone therapy drugs, including Premarin, Provera and Prempro, in that they:
- (i) Failed to prepare their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;
 - (ii) Failed to design their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;
 - (iii) Failed to conduct adequate pre-clinical testing and research to determine the safety of their hormone therapy drugs;
 - (iv) Failed to conduct adequate post-marketing surveillance to determine the safety of their hormone therapy drugs;
 - (v) Failed to accompany their products with proper warnings regarding all possible adverse side effects associated with the use of their hormone therapy drugs and the comparative severity and duration of such adverse effects;

- (vi) Failed to develop their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;
- (vii) Failed to manufacture their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;
- (viii) Failed to inspect their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;
- (ix) Failed to label their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;
- (x) Failed to market their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;
- (xi) Failed to promote their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;
- (xii) Failed to sell their hormone therapy drugs appropriately to prevent the aforementioned risks to individuals when the drugs were ingested;
- (xiii) Failed to provide adequate training and information to healthcare providers for the appropriate use of their hormone therapy drugs;
- (xiv) Failed to warn Plaintiff and her healthcare providers, prior to actively encouraging and promoting the sale of their hormone therapy drugs, either directly or indirectly, orally or in writing, about the following:
 - the need for comprehensive, regular medical monitoring to insure early discovery of potentially fatal strokes, heart attacks, venous thromboembolism, cardiovascular disease, breast cancer, ovarian cancer, and other adverse side effects;
 - the possibility of becoming disabled as a result of the use of the drugs;

- the adverse side effects associated with the use of the drugs, including, but not limited to, strokes, heart attacks, venous thromboembolism, cardiovascular disease, breast cancer, and ovarian cancer; and,

(xv) Were otherwise careless and negligent.

93. Despite the fact that Defendants knew or should have known that their hormone therapy drugs caused unreasonable and dangerous side effects, which many users would be unable to remedy by any means, they continued to promote and market their drugs to consumers, including Plaintiff Jeanne LeBlanc, when there existed safer and more effective methods of countering the negative health effects of menopause, and of preventing osteoporosis and other disease states claimed by Defendants to be prevented by its hormone therapy.
94. Defendants knew or should have known that consumers generally, and Plaintiff Jeanne LeBlanc specifically, would foreseeably suffer injury as a result of these Defendants' failure to exercise ordinary care.
95. Plaintiff Jeanne LeBlanc is entitled to punitive damages because Defendants' failure to warn was reckless and without regard for public safety and welfare. Defendants misled both the medical community and the public at large, including Plaintiff Jeanne LeBlanc, by falsely representing the safety of their products. Defendants downplayed, understated, and disregarded their knowledge of the serious and permanent side effects associated with the use of hormone therapy drugs despite available information demonstrating that their products were likely to cause serious and sometimes fatal side effects to users.
96. Defendants were or should have been in possession of evidence demonstrating that their products caused serious side effects. Nevertheless, Defendants continued to market their products by providing false and misleading information with regard to their safety and efficacy.
97. Defendants' actions described above were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff Jeanne LeBlanc and the public.
98. As a result of Defendants' conduct, Plaintiff Jeanne LeBlanc suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, the amount of Ten Million Dollars (\$10,000,000.00) in compensatory damages, and Twenty Million Dollars (\$20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

COUNT II – STRICT PRODUCTS LIABILITY

99. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:
100. Defendants are manufacturers and/or suppliers of hormone therapy drugs, and placed these drugs into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the product.
101. The hormone therapy drugs manufactured and/or supplied by Defendants were defective in design or formulation in that, when they left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.
102. The hormone therapy drugs were expected to and did reach Plaintiff Jeanne LeBlanc without substantial change in condition. Alternatively, the hormone therapy drugs manufactured and/or supplied by Defendants were defective in design or formulation, in that when they left the hands of the manufacturers and/or suppliers, they were unreasonably dangerous and more dangerous than an ordinary consumer would expect.
103. The hormone therapy drugs manufactured and/or supplied by Defendants were defective due to inadequate warning and/or inadequate clinical trials, testing and study, and inadequate reporting regarding the results of it.
104. The hormone therapy drugs manufactured and/or supplied by Defendants were defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from their hormone therapy drugs, they failed to provide adequate warnings to the medical community and women, and continued to promote the products as safe and effective.
105. The hormone therapy drugs were manufactured, distributed, tested, sold, marketed, advertised and represented defectively by the Defendants and such defects were substantial factors in bringing about the injuries to the Plaintiff Jeanne LeBlanc.

106. As the direct and proximate cause of the defective condition of the hormone therapy drugs as manufactured and/or supplied by Defendants, and of their negligence, carelessness, other wrongdoing and actions described herein, Plaintiff Jeanne LeBlanc suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, the amount of Ten Million Dollars (\$10,000,000.00) in compensatory damages, and Twenty Million Dollars (\$20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

COUNT III – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

107. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:
108. Defendants are manufacturers and/or suppliers of hormone therapy drugs, and placed these drugs into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the product.
109. The hormone therapy drugs manufactured and/or supplied by Defendants were not accompanied by proper warnings to physicians, the medical community and women regarding all possible adverse side effects associated with the use of their hormone therapy drugs and the comparative severity and duration of such adverse effects.
110. The warnings and information given to the medical community and women did not accurately reflect the symptoms, scope or severity of the potential side effects.
111. Defendants failed to perform adequate testing which would have shown that their hormone therapy drugs possessed serious potential side effects with respect to which full and proper warnings, accurately and fully reflecting symptoms, scope and severity, should have been made.
112. The hormone therapy drugs manufactured and/or supplied by Defendants were defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury and death from hormone therapy drugs, they failed to provide adequate warnings to physicians or consumers. And despite their inadequate post-marketing warnings and instructions to physicians, the medical community, and consumers, Defendants continued to promote the products aggressively.

113. Had adequate warnings or instructions been provided, Plaintiff Jeanne LeBlanc would not have taken the drugs as she did, and would not have suffered harmful side effects.

114. As the direct and proximate cause of the defective condition of hormone therapy drugs as manufactured and/or supplied by Defendants, Plaintiff Jeanne LeBlanc suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, the amount of Ten Million Dollars (\$10,000,000.00) in compensatory damages, and Twenty Million Dollars (\$20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

COUNT IV – BREACH OF IMPLIED WARRANTY

115. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:

116. In the design, manufacture, marketing, distribution and sale of Premarin, Provera and Prempro, and in the provision of Premarin, Provera and Prempro to Jeanne LeBlanc, Defendants impliedly warranted to the public in general, and to Mrs. LeBlanc in particular, that the Premarin, Provera and Prempro designed, manufactured, marketed, distributed, and sold by them, or under their supervision, direction and control, was merchantable and reasonably fit and suitable for the ordinary purposes for which such goods are used, and that the product conformed to the standards imposed by law.

117. The Defendants breached their implied warranties of fitness and merchantability, insofar as Premarin, Provera and Prempro were placed into the stream of commerce in such a manner as to constitute an unreasonable danger and hazard to Jeanne LeBlanc when used for its intended purpose. Contrary to such implied warranty, the Defendants' hormone therapy drugs were not of merchantable quality or safe or fit for their intended use, because the products were and are unreasonably dangerous and unfit for the ordinary purposes for which they were sold.

118. Plaintiff Jeanne LeBlanc reasonably relied upon the skill and judgment of Defendants as to whether their hormone therapy drugs were of merchantable quality and safe and fit for their intended use.

119. As the direct and proximate cause of the breach of implied warranty, Plaintiff Jeanne LeBlanc suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in the amount of Ten Million Dollars (\$10,000,000.00) in compensatory damages, and Twenty Million Dollars (\$20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

COUNT V – BREACH OF EXPRESS WARRANTY

120. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:
121. In the design, manufacture, marketing, distribution and sale of Premarin, Provera and Prempro, and in the provision of Premarin, Provera and Prempro to Jeanne LeBlanc, Defendants expressly warranted to the public in general, and to Mrs. LeBlanc in particular, that the Premarin, Provera and Prempro designed, manufactured, marketed, distributed, and sold by them, or under their supervision, direction and control, was merchantable and reasonably fit and suitable for the ordinary purposes for which such goods are used, and that the product conformed to the standards imposed by law, and were safe and efficacious when used as intended.
122. These warranties came in the form of: (i) publicly-made written and verbal assurances of the safety and efficacy of hormone therapy drugs by Defendants, (ii) press releases, interviews and dissemination via the media of promotional information, the sole purpose of which was to create and increase demand for hormone therapy drugs, which utterly failed to warn of the risks inherent to the ingestion of hormone therapy; (iii) verbal assurances made by Defendants regarding hormone therapy, and the downplaying of any risk associated with the drugs; (iv) false and misleading written information, supplied by Defendants, and published in the *Physicians' Desk Reference* on an annual basis, upon which physicians were forced to rely in prescribing hormone therapy drugs during the period of Plaintiff's ingestion of hormone therapy drugs, including, but not limited to information relating the recommended duration of the use of the drugs; (v) promotional pamphlets and brochures published and distributed by Defendants and directed to consumers; and (vi) advertisements. The documents referred to in this paragraph were created by and at the direction of Defendants and, therefore, are in their possession and control.
123. The Defendants breached their express warranties of fitness and merchantability, insofar as Premarin, Provera and Prempro were placed into the stream of commerce in such a manner as to constitute an unreasonable danger and hazard to

Jeanne LeBlanc when used for its intended purpose. Contrary to such express warranties, the Defendants' hormone therapy drugs were not of merchantable quality or safe or fit for their intended use, because the products were and are unreasonably dangerous and unfit for the ordinary purposes for which they were sold. As such, Defendants' products were neither in conformity to the promises, descriptions or affirmations of fact made about these drugs nor adequately contained, packaged, labeled or fit for the ordinary purposes for which such goods are used.

124. Defendant thereafter breached their express warranties to Plaintiff Jeanne LeBlanc in violation of the applicable provisions of the state Uniform Commercial Code as amended by: (i) manufacturing, marketing, packaging, labeling, and selling hormone therapy to Plaintiff Jeanne LeBlanc in such a way that misstated the risks of injury, without warning or disclosure thereof by package and label of such risks to Plaintiff Jeanne LeBlanc or the prescribing physician or pharmacist, or without so modifying or excluding such express warranties; (ii) manufacturing, marketing, packaging, labeling, and selling hormone therapy to Plaintiff Jeanne LeBlanc, which failed to counteract the negative health effects of menopause in a safe and permanent manner and without injury; and (iii) manufacturing, marketing, packaging, labeling, and selling hormone therapy to Plaintiff Jeanne LeBlanc, thereby causing her serious physical injury and pain and suffering.
125. Plaintiff Jeanne LeBlanc reasonably relied upon the skill and judgment of Defendants as to whether their hormone therapy drugs were of merchantable quality and safe and fit for their intended use.
126. As the direct and proximate cause of the breach of expressed warranty, Plaintiff Jeanne LeBlanc suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, the amount of Ten Million Dollars (\$10,000,000.00) in compensatory damages, and Twenty Million Dollars (\$20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

COUNT VI – FRAUD

127. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further alleges:
128. Defendants, having undertaken to prepare, design, research, develop, manufacture, inspect, label, market, promote, and sell their hormone therapy drugs, including Premarin, Provera and Prempro, owed a duty to provide accurate and complete information regarding these products.
129. Defendants' advertising programs, by containing affirmative misrepresentations and omissions, falsely and deceptively sought to create the impression that the use of their hormone therapy drugs, including Premarin, Provera and Prempro, were safe for human use, had no unacceptable side effects, and would not interfere with daily life.
130. Defendants intentionally encouraged women in general, including Plaintiff Jeanne LeBlanc, to remain on hormone therapy for a longer period of time than Defendants knew or should have known was safe and effective.
131. Defendants purposefully concealed, failed to disclose, misstated, downplayed, and understated the health hazards and risks associated with the use of hormone therapy. Defendants, through promotional literature, deceived potential users and prescribers of the drugs by relaying only allegedly positive information, while concealing, misstating, and downplaying known adverse and serious health effects. Defendants falsely and deceptively kept relevant information from potential hormone therapy users and minimized prescriber concerns regarding the safety and efficacy of its drugs.
132. Plaintiff Jeanne LeBlanc justifiably relied to her detriment upon Defendants' intentional misrepresentations concerning their hormone therapy drugs.
133. In particular, in the materials disseminated by Defendants, it falsely and deceptively misrepresented or omitted a number of material facts regarding their hormone replacement drugs, including Premarin, Provera and Prempro, including, but not limited to, the following:
- (i) The presence and adequacy of the testing of its hormone therapy drugs, both pre-and post-marketing;
and,
 - (ii) The severity and frequency of adverse health effects caused by their hormone therapy drugs.

134. Plaintiff Jeanne LeBlanc is entitled to punitive damages because the failure of Defendants to warn was reckless and without regard for the public's safety and welfare. Defendants misled both the medical community and the public at large, including Plaintiff Jeanne LeBlanc, by making false representations about the safety of their hormone therapy drugs.
135. Defendants were or should have been in possession of evidence demonstrating that their products caused serious side effects. Nevertheless, Defendants continued to market their products by providing false and misleading information with regard to their safety and efficacy.
136. Defendants' actions, as described above, were performed willfully, intentionally, and with reckless disregard for the rights of Plaintiff Jeanne LeBlanc and the public.
137. As a result of Defendants' conduct, Plaintiff Jeanne LeBlanc suffered these injuries as described with particularity, above. WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, in the amount of Ten Million Dollars (\$10,000,000.00) in compensatory damages, and Twenty Million Dollars (\$20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

COUNT VII – CORPORATE RESPONSIBILITY:
JOINT VENTURES, PARENT/SUBSIDIARIES, AND/OR
SUCCESSOR CORPORATION

138. Plaintiffs repeat and reallege, as if fully set forth herein, each and every allegation contained in the above paragraphs and further allege:
139. As a result of their participation in various joint ventures, parent/subsidiary relationships, and/or successor corporations, Defendants are liable to Plaintiff.
140. As a result of their negligent supervision and actual supervision of various joint ventures, parent/subsidiary relationships, and/or successor corporations, Defendants are liable to Plaintiff.
141. As a result of the invalidity of various indemnification agreements, Defendants are liable to Plaintiff.
142. Defendants are liable to Plaintiff, as alter egos of their joint ventures, parent/subsidiary relationships, and/or successor corporations.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, the amount of Ten Million Dollars (\$10,000,000.00) in compensatory damages, and Twenty Million Dollars (\$20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

COUNT VIII – LOSS OF CONSORTIUM

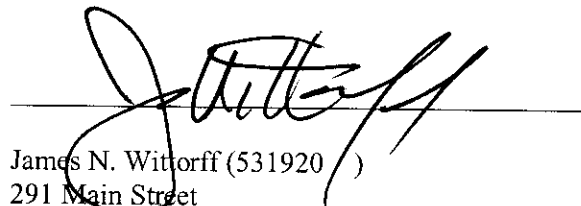
143. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein at length, and further allege:
144. Plaintiff Ronald J. LeBlanc was at all times relevant hereto the spouse of Plaintiff Jeanne LeBlanc, and lived and cohabited with her.
145. Mr. LeBlanc has necessarily paid and has become liable to pay for medical aid, treatment and for medications, and will necessarily incur further expenses of a similar nature in the future.
146. Mr. LeBlanc has been caused, presently and in the future, to suffer the loss of his spouse's companionship, services, society, and the ability of Mrs. LeBlanc, has in those respects been impaired and depreciated, and the marital association between husband and wife has been altered and, accordingly, has been caused great mental anguish.
147. Mr. LeBlanc is entitled to punitive damages because Defendants' failure to warn was reckless and without regard for the public's safety and welfare. Defendants misled both the medical community and the public at large, including Plaintiffs herein, by making false representations about the safety of their products. Defendants downplayed, understated and disregarded their knowledge of the serious and permanent side effects associated with the use of hormone therapy, despite available information demonstrating their products were likely to cause serious and sometimes fatal side effects to its users.
148. Accordingly, the Plaintiffs seek and are entitled to compensatory and punitive damages in an amount to be determined at trial.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, the amount of Ten million dollars (\$10,000,000.00) in compensatory damages, and Twenty Million Dollars (\$20,000,000) in punitive damages, plus interest, attorneys' fees and costs.

DEMAND FOR JURY TRIAL

Plaintiffs Jeanne LeBlanc and Ronald J. LeBlanc hereby demand a jury trial on all claims so triable in this action.

Respectfully submitted,
LAW OFFICE OF JAMES N. WITTORFF, P.C.



James N. Wittorff (531920)
291 Main Street
Milford, Massachusetts 01757
(508) 634-0009
(508) 634-8999 (Fax)

and

Robert K. Jenner
Kenneth M. Suggs
Janet, Jenner & Suggs, LLC
1829 Reisterstown Road
Suite 320
Baltimore, Maryland 21208
(410) 653-3200
(410) 653-6903 (Fax)

Attorneys for Plaintiff

JS 44 (Rev. 11/04)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings and other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1977, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS Jeanne and Ronald J. LeBlanc	DEFENDANTS Wyeth, Inc., et al.
(b) County of Residence of First Listed Plaintiff <u>Worcester</u> (EXCEPT IN U.S. PLAINTIFF CASES)	County of Residence of First Listed Defendant _____ (IN U.S. PLAINTIFF CASES ONLY)
(c) Attorney's (Firm Name, Address, and Telephone Number)	Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)	III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)																								
<input type="checkbox"/> 1 U.S. Government Plaintiff <input type="checkbox"/> 2 U.S. Government Defendant <input type="checkbox"/> 3 Federal Question (U.S. Government Not a Party) <input checked="" type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th></th> <th>PTF</th> <th>DEF</th> <th></th> <th>PTF</th> <th>DEF</th> </tr> <tr> <td>Citizen of This State</td> <td><input checked="" type="checkbox"/> 1</td> <td><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business In This State</td> <td><input type="checkbox"/> 4</td> <td><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td><input type="checkbox"/> 2</td> <td><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td><input type="checkbox"/> 5</td> <td><input checked="" type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td><input type="checkbox"/> 3</td> <td><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td><input type="checkbox"/> 6</td> <td><input type="checkbox"/> 6</td> </tr> </table>		PTF	DEF		PTF	DEF	Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
	PTF	DEF		PTF	DEF																				
Citizen of This State	<input checked="" type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4																				
Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5																				
Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6																				

IV. NATURE OF SUIT (Place an "X" in One Box Only)					
CONTRACT <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	FORFEITURE/PENALTY <input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	BANKRUPTCY <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark	OTHER STATUTES <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 449 Other Civil Rights	PRISONER PETITIONS <input type="checkbox"/> 510 Motions to Vacate Sentence Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	

V. ORIGIN (Place an "X" in One Box Only)							
<input checked="" type="checkbox"/> 1 Original Proceeding	<input type="checkbox"/> 2 Removed from State Court	<input type="checkbox"/> 3 Remanded from Appellate Court	<input type="checkbox"/> 4 Reinstated or Reopened	<input type="checkbox"/> 5 Transferred from another district (specify)	<input type="checkbox"/> 6 Multidistrict Litigation	<input type="checkbox"/> 7 Appeal to District Judge from Magistrate Judgment	

VI. CAUSE OF ACTION	Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): Brief description of cause:
----------------------------	---

VII. REQUESTED IN COMPLAINT:	<input type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23	DEMAND \$	CHECK YES only if demanded in complaint: JURY DEMAND: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
-------------------------------------	--	------------------	---

VIII. RELATED CASE(S) IF ANY	(See instructions): JUDGE _____	DOCKET NUMBER _____
-------------------------------------	---------------------------------	---------------------

DATE _____ SIGNATURE OF ATTORNEY OF RECORD _____

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING FFP _____ JUDGE _____ MAG. JUDGE _____

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**05-40102**

1. Title of case (name of first party on each side only) Leblanc v. Wyeth, Inc., et al.
2. Category in which the case belongs based upon the numbered nature of suit code listed on the civil cover sheet. (See local rule 40.1(a)(1)).
- ☐ I. 160, 410, 470, 535, R.23, REGARDLESS OF NATURE OF SUIT.
- ☐ II. 195, 196, 368, 400, 440, 441-446, 540, 550, 555, 625, 710, 720, 730, 740, 790, 791, 820*, 830*, 840*, 850, 890, 892-894, 895, 950. *Also complete AO 120 or AO 121 for patent, trademark or copyright cases
- ☒ III. 110, 120, 130, 140, 151, 190, 210, 230, 240, 245, 290, 310, 315, 320, 330, 340, 345, 350, 355, 360, 362, 365, 370, 371, 380, 385, 450, 891.
- ☐ IV. 220, 422, 423, 430, 460, 480, 490, 510, 530, 610, 620, 630, 640, 650, 660, 690, 810, 861-865, 870, 871, 875, 900.
- ☐ V. 150, 152, 153.
3. Title and number, if any, of related cases. (See local rule 40.1(g)). If more than one prior related case has been filed in this district please indicate the title and number of the first filed case in this court.
4. Has a prior action between the same parties and based on the same claim ever been filed in this court?
YES ☐ NO ☒
5. Does the complaint in this case question the constitutionality of an act of congress affecting the public interest? (See 28 USC §2403)
YES ☐ NO ☒
If so, is the U.S.A. or an officer, agent or employee of the U.S. a party?
YES ☐ NO ☐
6. Is this case required to be heard and determined by a district court of three judges pursuant to title 28 USC §2284?
YES ☐ NO ☒
7. Do all of the parties in this action, excluding governmental agencies of the united states and the Commonwealth of Massachusetts ("governmental agencies"), residing in Massachusetts reside in the same division? - (See Local Rule 40.1(d)).
YES ☒ NO ☐
- A. If yes, in which division do all of the non-governmental parties reside?
Eastern Division ☐ Central Division ☒ Western Division ☐
- B. If no, in which division do the majority of the plaintiffs or the only parties, excluding governmental agencies, residing in Massachusetts reside?
Eastern Division ☐ Central Division ☐ Western Division ☐
8. If filing a Notice of Removal - are there any motions pending in the state court requiring the attention of this Court? (If yes, submit a separate sheet identifying the motions)
YES ☐ NO ☐

(PLEASE TYPE OR PRINT)

ATTORNEY'S NAME James N. WittorffADDRESS 291 Main Street, Milford, MA 01757TELEPHONE NO. 508-634-0009